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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/629,432

07/29/2003

Dennis P. Curran

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09/06/2006

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EXAMINER

BERCH, MARK L

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/629,432

Applicant(s)

CURRAN ET AL.

Examiner

Mark L. Berch

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14 and 40-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51 and 52 is/are allowed.
- 6) ☒ Claim(s) 14 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/27/2006 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Applicants have narrowed the claims to just two species, which were the two recited previously in claim 39. Applicants have broadened claim 14 to embrace all cancers.

Claims 14 and 40-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Pursuant to *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), one considers the following factors to determine whether undue experimentation is required: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples;

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and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. Some experimentation is not fatal; the issue is whether the amount of experimentation is “undue”; see *In re Vaeck*, 20 USPQ2d 1438, 1444.

The analysis is as follows:

(1) Breadth of claims.

(a) Scope of the compounds. Two species are covered.

(b) Scope of the diseases covered. The coverage is immense. There are hundreds and hundreds of diverse cancers, which exist in all parts of the body. Some of those set forth:

A. Melanoma is a general type of cancer, arising from cells which produce melanin, and again is distributed fairly widely in the body, including the regional lymph nodes, skin, liver, lungs, eye, brain, and mucous membranes of the genitalia, anus, oral cavity and other sites. A malignant Melanoma is a malignancy of melanocytes, and occurs most commonly in the skin, but can also appear beneath the nail plate, in the eyes, ears, GI tract, leptomeninges of the central nervous system, and oral and genital mucous membranes.

There are 4 major types: superficial spreading, nodular, lentigo maligna, and acral lentiginous melanoma. There are a number of uncommon forms as well:

Desmoplastic/neurotropic melanoma, Mucosal (lentiginous) melanoma, Malignant blue nevus, Melanoma arising in a giant congenital nevus, and Melanoma of soft parts (a kind of clear cell sarcoma). In addition, there are Amelanotic melanomas, which are nonpigmented.

B. There are several main types of stomach cancers, which are very different from each other. (1) Lymphomas of the stomach are cancers of the immune system tissue that are

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found in the wall of the stomach. These come in two main categories. One is the Non-Hodgkin's lymphomas of the stomach, including MALT lymphoma, and assorted Large Cell Lymphoma of the Stomach such as anaplastic CD30 (Ki-1) positive large cell lymphoma (ALCL). The other is Hodgkin Lymphoma in the Stomach. These include both lymphomas which are primary to the stomach, and nodal lymphomas that have spread to the stomach from e.g. the spleen or liver and are thus secondary. There are Tertiary gastric lymphomas as well. (2) Gastric stromal tumors (GISTs) develop from the tissue of the stomach wall. There are an assortments of these; GISTs vary from cellular spindle cell tumors to epithelioid and pleomorphic ones. (3) Carcinoid tumors are tumors of hormone-producing cells of the stomach. These are classified into are classified into those that are associated with hypergastrinemic states (type 1, atrophic gastritis, pernicious anemia); Zollinger-Ellison syndrome [ZES] tumors (type 2), and tumors without hypergastrinemia (type 3 or sporadic). (4) Carcinoma of the Stomach exists in five types: papillary, tubular, mucinous, signet-ring cell adenocarcinoma and undifferentiated carcinoma. (5) Soft tissue sarcomas, most notably leiomyosarcoma of the stomach. There are other tumors as well, including Gastric Lipoma, gastric xanthelasma, and benign reactive lymphoid hyperplasia (pseudolymphoma).

C. There are many types of colon cancers, and this category is rather diverse. Most are adenocarcinomas, either of the mucinous (colloid) type or the signet ring type. Less common colon cancers include squamous cell, neuroendocrine carcinomas, carcinomas of the scirrhus type, lymphomas, melanomas, sarcomas (including fibrosarcomas and Leiomyosarcomas), and Carcinoid tumors. Because these are fundamentally different types

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of tumors, their treatment greatly differs, although adenocarcinomas and squamous cell tend to be treated the same.

D. Breast cancers come in great variety. The most important category of breast cancers is the ductal cancers. These come in a wide variety of types. Presently, these are divided into the following categories: Intraductal (in situ); Invasive with predominant intraductal component; Invasive, NOS; Comedo; Inflammatory (IBC); Medullary with lymphocytic infiltrate; Mucinous Carcinoma (colloid carcinoma); Papillary carcinoma; Scirrhus; Tubular; and Other. Another category is the Lobular breast cancers, which can be in situ, Invasive with predominant in situ component, and Invasive. There is Paget's disease of the Nipple, which can be also with intraductal carcinoma or with invasive ductal carcinoma. There is Adenomyoepithelioma, a dimorphic tumor characterized by the presence of both epithelial and myoepithelial cells. There is breast angiolipoma and spindle cell lipoma of the breast. There is lymphoma of the breast (which exists in both Non-Hodgkin's lymphoma of the breast and Hodgkin's disease of the breast forms). There are some sarcomas, including giant cell sarcoma of the breast, leiomyosarcoma of the breast, Angiosarcoma of the breast, cystosarcoma phylloides, and liposarcoma of the breast. There are carcinoid tumors which can be primary carcinoid tumors of the breast, or can arise from nonmammary sources. There are breast salivary gland-like tumors, including acinic cell carcinoma (AcCC), oncocytic carcinoma (Mammary epithelial oncocytoma), and mucoepidermoid carcinoma (MEC). Other rare carcinomas include Spindle cell carcinoma of the breast (SpCC), Squamous cell carcinoma of the breast, Secretory Carcinoma of the Breast (Juvenile secretory carcinoma), Metaplastic carcinoma of the breast (a heterogeneous group of invasive breast cancers including types with squamous

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differentiation and those with heterologous elements), Invasive Micropapillary Carcinoma of the Breast, Adenoid cystic carcinoma of the breast, cribriform carcinoma, Myofibroblastoma of the Breast (Benign spindle stromal tumor of the breast) and glycogen-rich clear cell carcinoma of the breast. There are numerous other rare breast cancers, including for example Fibromatosis of the breast (extra-abdominal desmoid), Angiomatosis of the Breast, and mammary hamartoma. There are also nonmammary tumors, primarily adenocarcinomas, that can metastasize to the breast including bronchogenic carcinomas, malignant melanomas, rhabdomyosarcomas, malignant mesotheliomas, thyroid carcinomas, renal cell carcinomas, malignant lymphomas, and gastrointestinal carcinomas (including those from the stomach, pancreas, esophagus, and colon).

E. Leukemia is any malignant neoplasm of the blood-forming tissues. Leukemia can arise from many different sources. These includes viruses such as EBV, which causes Burkitt's lymphoma, and HTLV-1, linked to certain T cell leukemias. Others are linked to genetic disorders, such as Fanconi's anemia, which is a familial disorder, and Down's Syndrome. Other leukemias are caused by exposure to carcinogens such as benzene, and some are actually caused by treatment with other neoplastic agents. Still other leukemias arise from ionizing radiation, and many are idiopathic. Leukemias also differ greatly in the morphology, degree of differentiation, body location (e.g. bone marrow, lymphoid organs, etc.) There are dozens of leukemias. There are B-Cell Neoplasms such as B-cell prolymphocytic leukemia and Hairy cell leukemia (HCL, a chronic leukemia). There are T-Cell Neoplasms such as T-cell prolymphocytic leukemia, aggressive NK cell leukemia, and T-cell granular Lymphocytic leukemia. There are different kinds of acute myeloid leukemias, acute promyelocytic leukemias, acute myelomonocytic leukemia, chronic

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myelomonocytic leukemia, acute monocytic leukemias, and erythroleukemias. There is also acute megakaryoblastic leukemia, acute promyelocytic leukemia, Multiple Myeloma, lymphoblastic leukemia, hypocellular acute myeloid leukemia, Ph-/BCR- myeloid leukemia, acute basophilic leukemia, and acute myelofibrosis. Chronic leukemias include chronic lymphocytic leukemia (CLL, which exists in a B-cell and a T-cell type), prolymphocytic leukemia(PLL), large granular lymphocytic leukemia (LGLL, which goes under several other names as well), chronic myelogenous leukemia(CML), chronic myelomonocytic leukemia, chronic granulocytic leukemia, chronic neutrophilic leukemia, chronic eosinophilic leukemia and many others.

F. The main types of lung and pleural cancer are small cell (i.e. oat cell, including combined oat cell), adenocarcinoma (Bronchioloalveolar carcinomas (Nonmucinous, Mucinous, and Mixed mucinous and nonmucinous or indeterminate cell type), Acinar, Papillary carcinoma, Solid adenocarcinoma with mucin, Adenocarcinoma with mixed subtypes, Well-differentiated fetal adenocarcinoma, Mucinous (colloid) adenocarcinoma, Mucinous cystadenocarcinoma, Signet ring adenocarcinoma, and Clear cell adenocarcinoma), squamous cell (Papillary, Clear cell, Small cell and Basaloid), mesothelioma (including epithelioid, sarcomatoid, desmoplastic and biphasic) and Large Cell Carcinoma (which include Large-cell neuroendocrine carcinoma, Combined large-cell neuroendocrine carcinoma, Basaloid carcinoma, Clear cell carcinoma Lymphoepithelioma-like carcinoma, and Large-cell carcinoma with rhabdoid phenotype). In addition there are also the carcinomas with pleomorphic, sarcomatoid or sarcomatous elements, including Carcinomas with spindle and/or giant cells, Spindle cell carcinoma, Carcinosarcoma and Pulmonary blastoma. The non-small cell lung carcinomas also include Adenosquamous carcinoma, the

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Carcinoid tumor (both typical Carcinoid and atypical Carcinoid) as well as carcinomas of salivary-gland type, including mucoepidermoid carcinoma and adenoid cystic carcinoma. There are some soft tissue tumors including localized fibrous tumor (formerly called benign fibrous mesothelioma); epithelioid haemangioendothelioma; pleuropulmonary blastoma; chondroma; calcifying fibrous pseudotumor of the visceral pleura); congenital peribronchial myofibroblastic tumors, diffuse pulmonary lymphangiomyomatosis and desmoplastic round cell tumor. There are assorted bronchial adenomas (eg, adenoid cystic carcinomas, mucoepidermoid carcinomas, mucous gland adenomas, and oncocyotomatous bronchial mucous gland adenoma) as well as other adenomas, including papillary adenoma. There are some papillomas, including squamous cell papilloma and glandular papilloma. There is also malignant melanoma of the lung, Hamartoma, some germ cell tumors, thymoma and sclerosing haemangioma and many others as well.

G. Ovarian cancers are a heterogeneous group of tumors. The most important are the epithelial tumors. These are themselves fairly diverse, the categories being Serous cystomas (Serous benign cystadenomas, Serous cystadenomas with proliferating activity of the epithelial cells and nuclear abnormalities but with no infiltrative destructive growth and Serous cystadenocarcinomas); Mucinous cystomas (divided the same three ways); Clear cell tumors (mesonephroid tumors, again divided the same way), Endometrioid tumors (similar to adenocarcinomas in the endometrium: Endometrioid benign cysts, Endometrioid tumors with proliferating activity of the epithelial cells and Endometrioid adenocarcinomas), mixed mesodermal (now considered to be carcinomas with areas of sarcomatous differentiation), clear cell, transitional cell, and mixed epithelial. Second, there are the Granulosa-Stromal Cell Tumours. These include the Granulosa cell tumor

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(which exists in juvenile and adult forms) and the tumors in the thecoma-fibroma group. This includes thecoma-fibroma group typical thecoma and luteinized thecoma or "stromal Leydig cell tumour". This also includes fibroma, cellular fibroma, fibrosarcoma, stromal tumour with minor sex cord elements, sclerosing stromal tumour, signet ring cell stromal tumor and others. Third, there are the Sertoli-Leydig Cell Tumours and Androblastomas. These include the Sertoli cell tumour (tubular androblastoma), Sertoli-Leydig cell tumour, a poorly differentiated sarcomatoid, tumor and a Retiform tumor. Fourth, there are some miscellaneous Sex Cord Stromal Tumors, including Gynandroblastoma of the ovary (composed of sex cord and stromal cells of both ovarian and testicular types), Sex Cord Tumor with Annular Tubules, Stromal luteoma, and Leydig cell tumor) which comes in hilus and non-hilar types). Fifth, there are an assortment of Germ Cell Tumors. These include Dysgerminoma; Yolk Sac Tumours (Endodermal Sinus Tumour, and Polyvesicular vitelline tumour, Hepatoid and others); Embryonal Carcinoma; Polyembryoma; Choriocarcinoma and a wide variety of Teratomas. These teratomas include immature, cystic (dermoid cyst), retiform (homunculus), and Monodermal, including struma ovarii, carcinoid (insular and trabecular), struma carcinoid, mucinous carcinoid, neuroectodermal tumours, sebaceous tumours and others. Finally, there are an assortment of other tumors which do not fit into the above categories. There is Gonadoblastoma and Tumours of Rete Ovarii (which can be Adenomatoid tumour or a Mesothelioma). There are some tumours of Uncertain Origin, including Small cell carcinoma, tumors of probable Wolffian origin, a Hepatoid carcinoma and Oncocytoma. There are some Soft Tissue Tumors not Specific to Ovary, and there are assorted malignant Lymphomas and Leukemias which land up in the ovaries.

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H. There are many types of colon cancers, and this category is rather diverse. Most are adenocarcinomas, either of the mucinous (colloid) type or the signet ring type. Less common colon cancers include squamous cell, neuroendocrine carcinomas, carcinomas of the scirrhus type, lymphomas, melanomas, sarcomas (including fibrosarcomas and Leiomyosarcomas), and Carcinoid tumors.

I. In addition, Claim 49 recites solid tumors. A Solid tumor is any cancer except hematopoietic (blood-origin) tumors. Thus, it includes most the above and much, much more. Since leukemia is already covered by claim 14, the claims in effect cover nearly all cancers.

(2) The nature of the invention and predictability in the art: The invention is directed toward medicine and is therefore physiological in nature. It is well established that “the scope of enablement varies inversely with the degree of unpredictability of the factors involved,” and physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

(3) Direction or Guidance: That provided is deficient. The daily dosage range information was omitted from the specification. The traverse is unpersuasive. Applicants point to the specification, page 10, but this does not provide a daily dosage. It just gives the size of a dose. There is no way of telling how many times per day (or per course of treatment) this dose is to be taken. And it is completely generic, as it does not state which of the hundreds of cancers it refers to.

(4) State of the Prior Art: The claimed compounds are camptothecins. No camptothecin has ever been found to be effective against any of these categories generally. The remarks state that the CPT class of compound “has been demonstrated to be effective against a broad

spectrum of tumors and leukemia.” Where is this demonstration? Where is there evidence for example that such compounds are effective against e.g. lymphomas of the stomach, squamous cell cancer of the colon, hairy cell leukemia , or mesothelioma of the lung? For example, the sentence and claim 14 mentions leukemia. It is true that in the 1990s, topotecan was investigated for acute myelogenous Leukemia and chronic myelomonocytic Leukemia. So far as the examiner is aware, topotecan was never establish as effective for any form of leukemia, and has not been approved for such use. And even if it were, these are just two of many, many forms of leukemia. As for irinotecan, even less work has been done there. Claim 42 recites malignant melanoma, of which there are several kinds. Melanomas generally do not respond to chemotherapy, except for biologics such as interferons. The paragraph bridging pages 9-10 refers to testing, but no actual data is provided. Applicants are reminded that “enhancing” the cleavage of this or that is far different from the actual treatment of cancer, let alone vast categories of cancer, as these claims call for.

(5) Working Examples: No actual working examples for the treatment of cancer are presented. Data appears for 3 cell lines. However, one cell line cannot possible demonstrate leukemia generally, and one cannot demonstrate lung generally, given the huge diversity of leukemias and lung cancers.

(6) Skill of those in the art: The prior art knows that there never has been a compound capable of treating cancer generally. There are compounds that treat a modest range of cancers, but no one has ever been able to figure out how to get a compound to be effective against cancer generally, or even a majority of cancers. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. “The cancer therapy art

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remains highly unpredictable, and no example exists for efficacy of a single product against tumors generally.”

(<http://www.uspto.gov/web/offices/pac/dapp/lpecba.htm#7>) **ENABLEMENT**

DECISION TREE, Example F, situation 1) Even the most broadly effective antitumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because cancers arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures of the body's cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Even those that affect just a single organ are often not generally treatable. Since it is beyond the skill of oncologists today to get an agent to be effective against cancers generally, evidence that the level of skill in this art is low relative to the difficulty of such a task. The skill thus depends on the particular cancer involved. One skilled in the art knows that chemotherapy of brain tumors is especially difficult. This is because 1) the blood-brain barrier, which is often intact in parts or all of a brain tumor, will block out many drugs, as it is the purpose of the blood-brain barrier to protect the brain from alien chemicals, and 2) CNS tumors are characterized by marked heterogeneity, which greatly decreases vulnerability to chemotherapy. As a result, many categories of CNS tumors simply have no chemotherapy available. These include, generally, hemangiomas and hemangioblastomas, low grade gliomas, meningiomas, craniopharyngiomas, acoustic neuromas, pituitary adenomas, optic nerve gliomas, glomus jugulare tumors and chordomas, to name just some. There are cancers where the skill level is high and there are multiple successful chemotherapeutic

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treatments. In many, many cancers, however, there is no chemotherapy whatsoever available. No compound has ever been found effective generally against leukemias, lung cancers, melanomas, etc because they are simply too diverse. Lymphomas of the stomach are not commonly treated with ordinary anti-cancer agents, but instead, surgery or radiation or antibiotic therapy(e.g. amoxicillin, metronidazole, bismuth, omeprazole) are the Primary Treatments. Treatment of malignant melanoma is normally with surgery or biological agents. Chemotherapy with non-biologics has a very limited role. The great majority of prostate cancers are not treatable with pharmaceuticals. Indeed, the majority of common cancers do not respond to chemotherapy.

(7) The quantity of experimentation needed: Given the fact that historically the development of new cancer drugs has been difficult and time consuming, and especially in view of factors 1 and 6, the quantity of experimentation needed is expected to be great.

MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, THIS ACTION IS MADE FINAL even though it is a first action after the filing of a request for continued

examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300 for regular communications and (571) 273-8300 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

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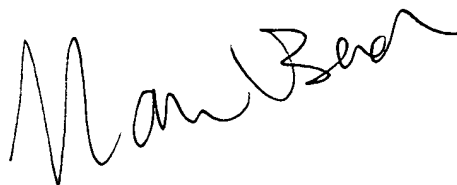
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Mark L. Berch

Primary Examiner

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A handwritten signature in black ink, appearing to read "Mark L. Berch". The signature is written in a cursive, flowing style with a large initial "M" and a long, sweeping underline.